Amendments to the Drawings:

The attached replacement drawing sheets make changes to Figs. 1-16 and replace the original sheets with Figs. 1-16.

Attachments: Replacement Sheets

REMARKS

Claims 1, 7, 9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51 and 60-66 are pending.[1] Claim 8 is canceled, claims 65 and 66 are added and the drawings are amended herein.

The attached paper copy and computer-readable copy of the Sequence Listing are submitted in compliance with 37 C.F.R. §§1.821-1.825. The contents of the paper copy and the computer-readable copy of the Sequence Listing are the same. No new matter is added.

Figures 13-16 are objected to for being illegible. Replacement drawing sheets of these figures are attached. The replacement figures also incorporate the changes proposed in the Request for Approval of Drawing Corrections filed July 16, 2001, and address the issues raised in the Notice of Draftperson's Patent Drawing Review attached to the Office Action mailed December 26, 2002. To comply with the margin requirements, nucleotides 751-800 and the corresponding amino acids have been moved from the bottom of Figures 7A and 8A to the tope of Figures 7B and 8B, respectively. It is respectfully requested that the Examiner approve the new drawings.

Claims 1, 14, 15, 26, 28-30, 45-47, 49-51, and 60-64 are objected to for including an allegedly non-elected nucleotide sequence. Applicants respectfully traverse the objection.

As described in Example 3 of the present application, SEQ ID NO: 12 relates to the 5M6 clone, which contains a region corresponding to the 3' region of the MSRV-1 envelope of 492 followed by the regions U3, R and U5 (837) of MSRV1. ¶¶ [0087]-[0088]. In particular, nucleotides 1-342 of SEQ ID NO: 12 are substantially similar to nucleotides 1140-1481 of SEQ ID NO: 9. In addition, nucleotides 257-873 of SEQ ID NO: 12 are substantially similar to nucleotides 1-617 of SEQ ID NO: 6. See, in particular, the attached Sequence Comparisons, which compare nucleotides 1-86 of SEQ ID NO: 6, nucleotides 1396-1481 of SEQ ID NO: 9 and nucleotides 257-342 of SEQ ID NO: 12. Thus, nucleotides 1-873 of SEQ

[1] It is noted that claim 26 is not listed among the pending claims in the Office Action's summary, although this claim is pending.

ID NO: 12 are substantially similar to nucleotides 1140-2012 of Figure 13, which is an envelope gene generated from SEQ ID NOs: 9 and 6. See ¶ [0081].

The Amendment filed March 24, 2004 is objected to under 35 U.S.C. §132 for allegedly introducing new matter into the disclosure. The Sequence Listing filed herewith deletes SEQ ID NO: 46. Therefore, the new matter objection should be withdrawn.

Claim 8 is rejected under 35 U.S.C. §112, second paragraph. In addition, claim 8 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. Claim 8 is canceled herein rendering these rejections moot.

Claims 1, 7-9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47 and 60-64 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. Applicants respectfully traverse the rejection.

To provide written description for a claim, the specification as originally filed must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventors were in possession of the invention as claimed. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. See, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Patent Office, therefore, must have a reasonable basis to challenge the adequacy of the written description. Specifically, the Patent Office has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the specification a description of the invention defined by the claims. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

In alleging that the specification does not provide written description for the claims, the Patent Office relies on a recent line of biotechnology cases that have held that merely

identifying a nucleic acid by its principle biological activity, such as reciting a DNA that encodes a particular protein, does not provide written description for that compound. Specifically, the Examiner relies on University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), which states that an adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

In Eli Lilly, the Federal Circuit held that a claim directed to human insulin cDNA was not adequately supported by the specification, which merely identified the cDNA by its principle biological activity, i.e., encoding human insulin, and a potential method for isolating it, without describing any structural features of the cDNA. 119 F.3d at 1567, 43 USPQ2d at 1404-05. In addition, the Federal Circuit held that the description of rat insulin cDNA was insufficient to support claims that generically recite vertebrate or mammalian insulin cDNA, which would, of course, encompass human as well as rat cDNA. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1405. Thus, in Eli Lilly, the Federal Circuit held that providing no structural information about the claimed human DNA was insufficient. However, the Federal Circuit has not held that it is necessary to set forth an exact nucleotide sequence for any sequence within the claim, much less for more than one embodiment within a claim, in order to fulfill the written description requirement, as is suggested in the Office Action. In fact, Eli Lilly clearly supports the opposite conclusion stating that an adequate written description "requires a precise definition, such as by structure, formula, chemical name, or physical properties," clearly indicating that something other than the exact formula can be sufficient to precisely define and thus provide written description for a nucleic acid.

Instead, what is required for written description is a precise definition of the nucleic acid "sufficient to distinguish [the claimed material] from other materials." Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1405. As discussed below, the present specification provides a precise

definition of the claimed nucleic acid in a manner that is sufficient to distinguish the claimed nucleic acids from other nucleic acids.

Unlike the situation in Eli Lilly, the present specification clearly provides more than a mere statement that the claimed nucleotide sequences are part of the invention and reference to a potential method for isolating them. Instead, the specification clearly indicates that the inventors isolated and sequenced SEQ ID NOs: 6, 9 and 12. See Example 1, ¶¶ [0060]-[0071]; Example 2, ¶¶ [0072]-[0081]; and Example 3, ¶¶ [0082]-[0088].

In addition to describing these specific sequences, the specification specifically describes nucleotide sequences having at least 70% homology with the recited sequences, particularly with regard to every series of 100 contiguous monomers of the sequence. ¶ [0012]. This reference to nucleotide sequences having at least 70% homology with the recited sequences provides substantial structural information about all of the sequences within the present claims. In particular, the specification provides sufficient structural information to distinguish the claimed nucleic acids from nucleic acids that are outside the scope of the claims, as was required by the Federal Circuit in Eli Lilly. That is, even though the specification does not set forth the nucleotide sequence of every nucleic acid within the claims, one could easily identify by its nucleotide sequence whether a particular nucleic acid has at least 70% homology with the recited sequences and is thus within the scope of the present claims. As a result, the present situation can be clearly distinguished from the situation in Eli Lilly where a nucleic acid was identified merely by its principle biological activity. Instead, in the present case, the claimed nucleic acids are identified by distinguishing structural characteristics.

As further support for the claims, attached is a set of Sequence Comparisons comparing overlapping ranges of SEQ ID NOs: 6, 9 and 12. These Sequence Comparisons depict differences between nucleotides 1-86 of SEQ ID NO: 6 nucleotides 1396-1481 of SEQ ID NO: 9 and nucleotides 257-342 of SEQ ID NO: 12. The sequence comparison between SEQ ID NOs: 6 and 9 shows at least 11 mismatches in this 86 nucleotide region, thus

providing a sequence homology of about 87% at this region. Thus, the present application clearly depicts that there can be deviations among the sequencing of clones, which clearly supports the claimed recitations of percent homology.

For at least these reasons, it is respectfully submitted that the specification clearly supports the present claims. Therefore, the written description rejection should be reconsidered and withdrawn.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 7, 9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51 and 60-66 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

William P. Berridge
Registration No. 30,024

Melanie L. McCollum
Registration No. 40,085

WPB:MLM/jam

Attachments:
Sequence Listing (paper and computer-readable copies)
Replacement Sheets
Sequence Comparisons

Date: November 7, 2005

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Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry;
Charge any fee due to our Deposit Account No. 15-0461

SEQUENCE COMPARISONS

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6  ccctgtatctttaacctccttgttaagtttgtctcttccagaatcaaaactgtaaaactacaaattgttcttcaaatggagcacca
                                                ::  :       :     :  :  :: :        : :
9  ccctgtatctttaacctccttgttaagtttgtctcttccagaattgaagctgtaaagctacagatggtcttacaaatggaacccca


6  ccctgtatctttaacctccttgttaagtttgtctcttccagaatcaaaactgtaaaactacaaattgttcttcaaatggagcacca
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9  ccctgtatctttaacctccttgttaagtttgtctcttccagaattgaagctgtaaagctacagatggtcttacaaatggaacccca
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